K123945

APR 17 2013

510(k) SUMMARY

Date Prepared: March 12, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Submitter Information

Name:	Monaghan Medical Corporation
Address:	5 Latour Avenue; Suite 1600
	Plattsburgh, New York 12901
Telephone#:	518-561-7330
Fax#:	518-561-5660
Contact Person:	Cari J. Reil
	Regulatory Affairs Manager

2. Device Information

Device Trade Name:	***Strive***™ Dual Zone Peak Flow Meter
Common Name:	Peak Flow Meter
Classification Name:	Peak-flow meter for spirometry
Classification Number:	868.1860
Classification Product Code:	BZH

3. Legally Marketed Predicate Device

Device Trade Name:	***TruZone***® Peak Flow Meter
510(k) Number:	K023097
Manufacturer:	Monaghan Medical Corporation

4. Device Description

The ***Strive***™ Dual Zone Peak Flow Meter (PFM) is a hand-held monitoring device that measures Peak Expiratory Flow (PEF) generated by the patient during a forced exhalation maneuver. It can be used to objectively measure PEF by tracking day-to-day changes in breathing patterns.

The ***Strive***™ PFM meets the Standards of Spirometry, 2005 revision, for portable peak flow meters as established by the American Thoracic Society and also meets ISO23747, First edition 2007-07-15, for Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans. The ***Strive***™ PFM and product insert meets the educational guidelines recommended by the National Asthma Educational Prevention Program (NAEPP) of the National Institutes of Health.

The ***Strive***™ PFM has two scale ranges to make the device suitable for both pediatric (+5 yrs) and adult patients who use a peak flow meter as part of their treatment program for respiratory conditions. A range selector is used to select the scale that best fits the patient's needs as determined by a healthcare provider. The device incorporates the NAEPP three zone color codes. The color-coded zone indicators on the side of the device adjust to define the patient's red, yellow and green zones. They can be readjusted as recommended by a healthcare provider.

5. Intended Use

   The ***Strive***™ Dual Zone PFM is a monitoring device that measures Peak Expiratory Flow (PEF) generated by the patient during a forced exhalation maneuver. The device will monitor the PEF of patients whose doses of medication are dependent upon a measured obstruction in PEF.

   The ***Strive***™ Peak Flow Meter is designed for children five years or older and adults. The intended environments for use include home, hospitals and clinics.

6. Technological Characteristics

   The ***Strive***™ Dual Zone PFM has the same function and intended use as the predicate device, ***TruZone***® PFM.

   The ***Strive***™ PFM is a dual zone device suitable for both pediatric (5+ years) and adult patients who use a PFM as part of their treatment program. It has improved accuracy at low flow-rates.

   The device has color-coded zone markers that can be adjusted by the patient so readings can be taken quickly and easily and can be readjusted as recommended by their healthcare provider.

   The ***Strive***™ Dual Zone PFM has an ergonomically shaped mouthpiece to assist in creating a secure seal and has an optional disposable mouthpiece with one-way valve for clinical applications.

7. Non-Clinical Test Summary

   The ***Strive***™ Dual Zone PFM was tested for performance, including: Functional testing per the American Thoracic Society (ATS) Standard of Spirometry: 2005, ISO 23747 International Standard for peak expiratory meter, Environmental Testing, Operational Testing, Mechanical Life Cycle.

   The ***Strive***™ Dual Zone PFM meets the same ATS standard as the predicate device, the ***TruZone***® PFM. All other testing was found to be comparable to the ***TruZone***® PFM.

8. Clinical Performance Summary

   Clinical testing was not completed as it is not required to show substantial equivalence.

9. Conclusions

   The ***Strive***™ Dual Zone PFM meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Mr. Carl J. Reil
Regulatory Affairs Manager
Monaghan Medical Corporation
5 Latour Avenue, Suite 1600
PLATTABURGH NY 12901

Re: K123945
Trade/Device Name: Strive™ Dual Zone Peak Flow Meter (PFM)
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: March 12, 2013
Received: March 18, 2013

Dear Mr. Reil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
-S FDA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

monaghan

510(k) Number (if known): K123945

Device Name: ***Strive***™ Dual Zone Peak Flow Meter (PFM)

Indications for Use:

The ***Strive***™ Dual Zone PFM is a monitoring device that measures Peak Expiratory Flow (PEF) generated by the patient during a forced exhalation maneuver. The device will monitor the PEF of patients whose doses of medication are dependent upon a measured obstruction in PEF.

The ***Strive***™ Peak Flow Meter is designed for children five years or older and adults. The intended environments for use include home, hospitals and clinics.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S (for LS)
c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300059331, cn=Albert E. Moyal -S
2013.04.17 12:31:33 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123945

Prescription Use √ or Over-The-Counter Use ____

(Per 21 CFR 801.109)